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No. 96-188

IN THE

Supreme Court of the United States

OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY, *ET AL.*,
Petitioners,

v.

ROBERT K. JOINER, *ET AL.*,
Respondents.

**On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit**

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

What is the standard for appellate review of district court decisions excluding purported expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

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BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

INTEREST OF THE *AMICUS CURIAE* [1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the country's leading research-based

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[1] Pursuant to Supreme Court Rule 37.6, PhRMA hereby states that no counsel for a party has authored this brief in whole or in part, and that no person or entity, other than PhRMA or its members, has made a monetary contribution to the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3(a), the parties have consented to the filing of this brief. Their letters of consent have been filed with the Clerk of the Court.

pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA's member companies invest nearly $19 billion annually in discovering and developing new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

The pharmaceutical industry is based on science, from the discovery of promising new chemical entities through their testing, development, and distribution. Science also must play a vital role in product liability cases alleging injury from these products. Unless unreliable and speculative opinions are excluded, juries in these complex cases can award damages that are not founded on reliable scientific knowledge. Such awards threaten the enterprise of pharmaceutical research and development, and thus the availability of important new medicines.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), establishes the framework governing admission of scientific evidence to prevent unsupported theories from being presented to juries in the guise of expert testimony. It is vital for district courts to examine proffered testimony thoroughly and carefully, and to exclude testimony that does not meet *Daubert*'s demanding standards.

PhRMA has a strong interest in ensuring that the standard of appellate review established for a trial court's admissibility determinations under *Daubert* does not deter courts from excluding proffered evidence that is scientifically flawed. Accordingly, PhRMA is filing this brief to provide the Court its perspective on the standard of appellate review in the context of *Daubert*'s proper application in the district court, and on the serious consequences for the availability of medicines of unfounded product liability judgments.

SUMMARY OF ARGUMENT

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), requires trial courts to act as gatekeepers and to exclude from evidence proffered expert scientific testimony that lacks a sound scientific basis. In particular, *Daubert*, unlike the common law *Frye* test which the Federal Rules of Evidence superseded, directs district courts to conduct an independent assessment of the reliability and relevance of purportedly scientific evidence rather than to inquire merely whether the expert's methods are generally accepted in the scientific community. To carry out this charge in a meaningful manner, district courts must scrutinize each step in an expert's reasoning to ensure that the expert's opinions rest on a scientifically valid and pertinent foundation. The district court in the instant case performed an appropriately careful and searching review.

Such a rigorous application of *Daubert*'s framework is particularly important to safeguarding the development and availability of medicines. Pharmaceutical manufacturers face product liability claims that typically turn on scientific evidence regarding questions of causation that trigger *Daubert* and Federal Rule of Evidence 702. If courts permit unsupported pseudoscientific theories of causation to be presented to a jury, pharmaceutical firms could face baseless liability awards that would adversely affect the research and development of new medicines and the continued availability of existing ones. Accordingly, courts should be especially vigilant to exclude testimony that does not meet the *Daubert* standards and to grant summary judgment before trial where plaintiffs do not come forward with valid expert opinions to support their allegations.

The district courts should not be secondguessed by appellate courts when they carry out the complex inquiry

required by *Daubert*. Therefore, the courts of appeals should apply an abuse of discretion standard in reviewing decisions on the admissibility of scientific evidence. Less deferential review would only discourage district courts from performing their gatekeeper function under *Daubert*. In particular, the courts of appeals should not apply heightened scrutiny only to the exclusion of evidence, for such a one-way ratchet would provide a detrimental incentive to district courts to allow unsupported and scientifically flawed testimony to go to the jury.

ARGUMENT

I. *DAUBERT* REQUIRES THAT DISTRICT COURTS ACT AS GATEKEEPERS TO PREVENT PSEUDOSCIENTIFIC OPINIONS FROM REACHING THE JURY.

Daubert held that the Federal Rules of Evidence require trial judges to perform a "gatekeeping role" and screen purportedly scientific evidence to ensure that it is relevant and reliable. 509 U.S. at 589, 597. When a party proffers expert scientific evidence, the trial judge, in addition to qualifying a witness as an expert, must make a threshold determination "of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592-93. Courts must not permit claimed scientific opinions that amount to no more than unsupported assertions or speculation to reach the jury. *See Claar v. Burlington N. R.R.*, 29 F.3d 499, 502 (9th Cir. 1994); *see also Gruca v. Alpha Therapeutic Corp.*, 51 F.3d 638, 643 (7th Cir. 1995) (criticizing district court for abdicating its gatekeeping

responsibilities).[2/]

Although district courts screened proffered scientific evidence prior to *Daubert*, *Daubert* interpreted the Federal Rules of Evidence to alter a court's gatekeeping role in certain important respects. First, *Daubert* held that the Federal Rules of Evidence, and Rule 702 in particular, supersede the common law *Frye* test, which most courts followed before *Daubert*, and require district courts to conduct their own independent assessment of scientific evidence rather than to inquire merely whether the expert's methods are generally accepted in the scientific community. *Daubert*, 509 U.S. at 587, 589, 597; *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923); Eric D. Green & Charles R. Nesson, *Problems, Cases, and Materials on Evidence* 649 (1983). Second, *Daubert*, again based primarily on Federal Rule of Evidence 702, outlined an analytical framework for courts to follow in making threshold admissibility determinations. 509 U.S. at 589-95. As discussed further below, to apply this framework properly and take its reinvigorated gatekeeping responsibility seriously, a court must carefully assess each link in an expert's chain of reasoning to ensure that the expert's opinions are based on a valid scientific methodology and are applicable to the facts and issues of a particular case.

2/ As the Supreme Court explained in *Daubert*, significant differences exist between scientific inquiry and legal inquiry. Although consideration of wide-ranging hypotheses are part of science's search for truth, "[c]onjectures that are probably wrong are of little use . . . in the project of reaching a quick, final, and binding legal judgment — often of great consequence — about a particular set of events in the past." *Daubert*, 509 U.S. at 597.

A. Under *Daubert*, District Courts Must Independently Assess the Reliability and Relevance of Proffered Expert Scientific Testimony.

Daubert charges district courts with taking an active role in reviewing scientific evidence, in contrast to the deferential role of *Frye*. As the Seventh Circuit has explained, the elimination of the *Frye* standard "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom. It is a responsibility to be taken seriously." *Wilson v. City of Chicago*, 6 F.3d 1233, 1238-39 (7th Cir. 1993) (internal citation omitted), *modified on other grounds*, 1993 U.S. App. LEXIS 31,896 (7th Cir. Dec. 8, 1993), *cert. denied*, 511 U.S. 1088 (1994); *see also In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The *Daubert* Court significantly changed the standards governing the admissibility of scientific evidence by expanding district courts' discretion to evaluate the reliability and relevance of contested evidence."), *cert. denied*, 115 S. Ct. 1253 (1995); *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1315 (9th Cir.) ("Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before."), *cert. denied*, 116 S. Ct. 189 (1995) [hereinafter *Daubert II*]. No matter how credentialed the expert, the court must ensure that the expert's opinions are grounded in a sound and pertinent scientific foundation. *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318-19 (7th Cir.), *cert. denied*, 117 S. Ct. 73 (1996).

This responsibility derives from the plain language of Federal Rule of Evidence 702, which requires, in relevant part, that expert opinion testimony (1) consist of "scientific knowledge" and (2) "assist the trier of fact to understand the

evidence or to determine a fact in issue."[3] *Daubert*, 509 U.S. at 589-92. To qualify as "scientific knowledge" and satisfy the first prong of this two-pronged test, testimony must be "derived by the scientific method" and have a "grounding in the methods and procedures of science." *Id.* at 590. Only opinions so validated are sufficiently reliable to be admitted into evidence. To "assist the trier of fact" and satisfy the second prong of Rule 702, an expert's opinion must have "a valid scientific connection to the pertinent inquiry." *Id.* at 592. That is, an expert's opinion must not only be grounded in science and hence generally reliable, it must be based on reasoning or methodology that applies to the disputed issue in a particular case. Reasoning or methodology that does not "fit" the case at hand is not relevant and, thus, not admissible. *Id.* at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)).[4]

Daubert identifies four factors to guide a court's assessment of the scientific reliability and applicability of the theory or technique upon which the proffered scientific

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[3] In its entirety Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

[4] For example, as the Supreme Court explained in *Daubert*, expert testimony on the phases of the moon might be relevant to determining whether it was dark out on a given night, but would not be relevant to determining whether someone acted irrationally that night, unless credible evidence could validate the relationship between the phases of the moon and a person's behavior. 509 U.S. at 591.

evidence rests: (1) whether it can be tested empirically; (2) whether it has been subjected to peer review and publication; (3) what its error rate is; and (4) whether it has a high degree of general acceptance in the relevant scientific community. 509 U.S. at 593-94.[5/] Each factor can shed some light on the scientific validity of an expert's theory, and no single factor is determinative. *Id.* at 594-95. For example, although a theory or technique need not be generally accepted by other experts, as *Frye* required, minimal acceptance within the scientific community provides grounds for the court to view a theory skeptically. *Id.* at 594.

Daubert expressly provides that other factors, in addition to the four it outlines, might be germane to a court's scrutiny of scientific evidence, *id.* at 593, and courts have identified further relevant considerations. For example, the Ninth Circuit has held that developing an opinion solely for the purposes of litigation can cast doubt on its reliability, *Daubert II*, 43 F.3d at 1317, and the Third Circuit has held that courts can consider the degree to which an expert is qualified in evaluating whether his or her opinions are scientifically reliable, *In re Paoli*, 35 F.3d at 742.

Together these factors provide courts the means to scrutinize purportedly scientific evidence. However, they must be applied with rigor to carry out *Daubert*'s gatekeeping mandate properly, for "something doesn't become 'scientific

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[5/] Some courts treat these factors as applying only to the reliability determination. *See, e.g., In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994). In *Daubert*, this Court described the factors as relating to the overarching inquiry of whether testimony is *both* scientifically valid and applicable to the facts in issue. 509 U.S. at 593. Logically, the factors can assist a court's inquiry into both whether there is a valid basis for the expert's opinions in general, and whether there is a valid basis to apply those opinions to the facts of a particular case.

knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Daubert II*, 43 F.3d at 1315-16.

B. The Only Meaningful Way to Assess the Reliability and Relevance of Purported Expert Scientific Testimony is to Scrutinize Carefully Each Step in the Expert's Reasoning to Ensure that it is Scientifically Valid and Pertinent to the Case at Hand.

An expert's scientific opinion can only be sound if each step in the reasoning that led to the opinion is sound. As one court has explained, "an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Rosen*, 78 F.3d at 319 (quoting *Mid-State Fertilizer Co. v. Exchange Nat'l Bank*, 877 F.2d 1333, 1339 (7th Cir. 1989)). To assess the reliability and relevance of scientific expert testimony in any real way, a trial court must scrutinize each aspect of the methodology that an expert uses to reach a conclusion. *See In re Paoli*, 35 F.3d at 745 ("*[A]ny* step that renders the analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible.*") (emphasis in original); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1401 (D. Or. 1996) (the trial judge must "ensure that in each step, from initial premise to ultimate conclusion, the expert faithfully followed valid scientific methodology").

As a preliminary matter, the trial court must verify that an expert has an appropriate foundation upon which to draw a conclusion. Opinions consisting purely of untested hypotheses are inadequate to satisfy *Daubert*'s strictures. *See Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994) (expert's "hypothesis" that combination of medicines plaintiff took for her neck pain may have caused plaintiff's hepatitis

should be excluded where expert lacked empirical studies or any other basis for his opinion.); *Porter v. Whitehall Lab., Inc.*, 9 F.3d 607, 614 (7th Cir. 1993) (doctor's theory that ibuprofen caused plaintiff's renal condition properly excluded where doctor could not point to studies, records, data, or other scientific basis for her opinion). So too are opinions based solely on anecdotal evidence, *Bradley v. Brown*, 852 F. Supp. 690, 699 (N.D. Ind.) (notwithstanding the claim of plaintiffs' experts to have experience with over 20,000 cases of multiple chemical sensitivity disorder ("MCS"), the district court excluded the expert's opinion as to the cause of the plaintiffs' MCS because it "would necessarily rest on uncontrolled past observations" and was "a far cry from the tested hypotheses foreseen as the basis of 'scientific knowledge' . . . under Rule 702"), *aff'd*, 42 F.3d 434 (7th Cir. 1994),[9] and those based on potentially biased data, *In re Paoli*, 35 F.3d at 763 (upholding district court's exclusion of expert where expert relied on plaintiffs' answers to questionnaires and failed to examine plaintiffs or review their medical records).

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[9] *See also Bradley*, 42 F.3d at 438 (holding that experts' opinions as to cause could be excluded as "merely anecdotal"); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090, 1107 n.19 (7th Cir. 1994) (doctor's prior experience with five cases of radiation-induced cataracts not a proper basis for opinion); *Porter*, 9 F.3d at 614 n.6 (doctor's "experience and first-hand observations" held insufficient basis for opinion on causation where doctor had encountered only about five cases of relevant disorder, none of which was linked to the alleged cause claimed by plaintiff); *Wade-Greaux v. Whitehall Lab., Inc.*, 874 F. Supp. 1441, 1481 (D.V.I.) (rejecting reliance on "individual human case reports" because "such data represent anecdotal information of chance associations, do not purport to assess cause and effect and have no epidemiological significance"), *aff'd mem.*, 46 F.3d 1120 (3d Cir. 1994); *Casey v. Ohio Medical Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (expert's opinion could not be based on study that "was not an epidemiological study," but only "a compilation of case reports").

Similarly, courts have held that animal studies, without confirmation through rigorous epidemiological or other evidence in humans, do not provide a sufficient basis for an expert to assert causation in humans. For example, in *Raynor v. Merrell Pharmaceuticals Inc.*, the court of appeals held that the district court properly excluded an expert's opinion that Bendectin caused birth defects in part because the animal studies that the expert relied upon were contradicted by relevant epidemiological evidence. 104 F.3d 1371, 1375 (D.C. Cir. 1997). As the *Raynor* court explained, "[t]he only way to test whether data from non-human studies can be extrapolated to humans would be to conduct human experiments or use epidemiological data." *Id.*; *see also Daubert II*, 43 F.3d at 1320 (requiring experts to "point to some authority for extrapolating human causation" from animal studies); *Wade-Greaux*, 874 F. Supp. at 1480 ("[T]he theory of the plaintiff's expert witnesses that they can directly extrapolate from experimental animal studies without supportive positive human studies to opine on causation in humans is one that has an extraordinarily high rate of error.").

If a party can demonstrate that the foundation upon which its expert's conclusions rest is sufficiently reliable, the court must next examine whether the expert followed a scientifically valid reasoning process in drawing conclusions from that foundation. *Daubert* cautions that courts must focus on principles and methodology and not the substance of an expert's conclusions. 509 U.S. at 595. Nonetheless, even a limited inquiry into an expert's methodology must consider how the expert reached his or her conclusions from some established premise. As the dissenting judge in the decision below stated, "We should not require the trier of fact to accept blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusions. . . . [T]he trial court 'gatekeeper' has broad discretion to decide whether a leap of faith across the analytical gap is so

great that, without further credible grounds, the testimony is inadmissible." Pet. App. 18a (Smith, J., dissenting); *see also Hall*, 947 F. Supp. at 1411 ("[A]n evaluation of whether scientific methodology is valid for *Daubert* purposes should include an examination of how the proffered conclusions relate to the bases upon which the expert relies.").

For example, an expert cannot cite legitimate data as the basis of an opinion, but then selectively use such data to reach a conclusion. *See Daubert II*, 43 F.3d at 1320 (requirement that expert's methodology be based on "sound scientific principles" means that plaintiffs' epidemiologists would have to "validate their reanalyses by explaining why they chose only certain of the data that was available"); *In re Paoli*, 35 F.3d at 773 (reanalyzing data based on selection of limited samples "does not appear reliable"). Similarly, an expert's conclusion that some event caused a claimed effect is flawed where the expert fails to account for and rule out alternative causes. *See In re Paoli*, 35 F.3d at 768; *Claar*, 29 F.3d at 502; *Porter*, 9 F.3d at 616. Of course, an expert also cannot cite as the basis for a proposition some source that does not in fact support the expert's conclusions. For example, in *Conde v. Velsicol Chem. Corp.*, the court held that the plaintiffs' expert could not base his opinion that an insecticide caused long-term health effects on published critiques of negative epidemiological studies where the critiques merely called for further study and did not provide any affirmative support for the claimed causation. 24 F.3d 809, 814 (6th Cir. 1994).

Relatedly, under *Daubert*'s second prong (the "fit" test), courts must ensure that experts do not inappropriately apply otherwise reliable scientific evidence to contexts in which it is not relevant. In effect, when an expert overstates the relevance of scientific evidence in this manner, the expert renders his or her conclusions methodologically unsound and unreliable. For example, an expert's opinion that the

defendant's nicotine patch caused the plaintiff's heart attack amounted to no more than an "inspired [] hunch," even though he cited a potentially valid animal study that nicotine can cause arterial plaque in the long term, because the study could not explain how a nicotine overdose from the patch could have precipitated plaintiff's heart attack in the short term. *Rosen*, 78 F.3d at 319; *see also Hall*, 947 F. Supp. at 1411-12 (studies based on crystalline silica cannot support conclusions that breast implants caused disease given failure to establish that silicone gel in implants degrades to silica).

Courts must pay particular attention to relevance problems in cases turning on issues of causation. For example, evidence that exposure to a substance can cause harm in general does not provide a reliable basis for establishing that exposure caused a particular harm. *See, e.g., Casey*, 877 F. Supp. at 1385 (refusing to admit expert testimony that exposure to halothane could cause chronic active hepatitis because the study on which the expert based his opinion established only that halothane exposure might be harmful and might cause some liver disorders, not that such exposure could cause hepatitis). Similarly, evidence that exposure to a large dose of a substance can cause harm does not provide a reliable basis for establishing that harm can be caused by a lower dose. *See Porter*, 9 F.3d at 615 (excluding testimony that ibuprofen could aggravate an independently developed kidney problem where expert "admitted that this aggravation would be dose-related and would require a far greater dosage than [the deceased] ingested"); *Wade-Greaux*, 874 F. Supp. at 1454, 1457, 1464, 1480 (holding that the reliability of animal studies is undermined by the enormous dosages administered and characterizing as "untenable" expert's assumption that level of "dose is irrelevant to humans"); *Chikovsky v. Ortho Pharmaceutical Corp.*, 832 F. Supp. 341, 345-46 (S.D. Fla. 1993) (excluding doctor's testimony that Retin-A, a Vitamin A derivative, caused birth defects, where opinion was based

on studies linking "high doses" to fetal harm, but doctor admitted that he did "not know how much Retin-A [the plaintiff] might have absorbed through her skin during her pregnancy" and that he "did not know at what dosage level Vitamin A became unsafe for use by pregnant women"). More generally, an expert cannot stretch an opinion based on certain assumptions to a case where those assumptions have not been established. *See, e.g.*, *Pries v. Honda Motor Co.*, 31 F.3d 543, 545 (7th Cir. 1994) (excluding expert opinion that seatbelt latch had come open during accident, because although expert testified that latch could come open if it struck a hard surface, there was no evidence or opinion that similar forces occurred commonly in a crash).

Only by assessing each of these aspects of an expert's reasoning can a court ensure that the opinion is grounded in science. One weak link in an expert's methodological chain fatally flaws the conclusions that the methodology yields.

C. In the Instant Case, the District Court Properly Executed its Gatekeeping Function Under *Daubert*.

The contrast between the application of *Daubert* by the district court and by the court of appeals in this case is illustrative of the difference between a meaningful review of an expert's purportedly scientific methodology and a refusal to take seriously *Daubert*'s directive to admit only "scientific knowledge." Out of a misplaced concern for turning "judges into jurors or surrogate scientists," Pet. App. 7a, the court of appeals focused on whether the experts' opinions "as a whole" constituted mere speculation, Pet. App. 13a, rather than examining critically the foundation for and reasoning process used in reaching those opinions. The district court correctly questioned the animal studies that the plaintiffs' experts relied upon because there were only two studies, they involved massive doses of PCBs, and they were preliminary. Pet. App.

61a. The court of appeals, though, criticized the district court for focusing on "individual pieces of evidence," which should be viewed "in their entirety" as "building blocks of a perfectly reasonable conclusion." Pet. App. 12a. Yet, even if the court of appeals is correct that the ultimate inquiry is the reliability of an expert's final opinions, it is impossible for a court to make that ultimate determination without carefully examining the particulars upon which an opinion is based.

Notably, the court of appeals failed to offer an explanation for rejecting the district court's finding that the epidemiological studies were flawed because they were "either equivocal or not helpful to Plaintiffs," Pet. App. 63a, or that the animal studies could not support the plaintiffs' claims because they were performed with excessively high doses, Pet. App. 61a. Rather, the court of appeals simply noted that the experts "utilized numerous scientific studies and authorities," Pet. App. 10a, and it relied on the experts' own representations that they employed generally accepted and long-established methods and procedures to reach their conclusions, Pet. App. 10a-11a. As the concurrence makes explicit, the court of appeals refused to evaluate "[w]hether the conclusions advanced from the stated premises in fact follow . . . ." Pet. App. 16a (Birch, J., concurring). Presumably, then, under the approach of the court of appeals, an expert has free rein to offer opinions so long as he or she asserts that they flow from sources that the court has found valid. Such an approach would gut *Daubert* and Rule 702, and would allow an expert's unsupported contentions to masquerade as scientific opinion. In contrast, the district court's careful approach, examining particular claims and pieces of evidence to make an overall assessment of an expert opinion's reliability, correctly preserves the court's gatekeeping role.

II. THE PROPER APPLICATION OF *DAUBERT* BY DISTRICT COURTS IS PARTICULARLY IMPORTANT TO THE CONTINUED DEVELOPMENT AND AVAILABILITY OF MEDICINES.

The product liability claims that are brought against pharmaceutical companies typically turn on scientific evidence, and, in particular, on scientific evidence of causation, like the claim against the pharmaceutical manufacturer in *Daubert* itself. As such, they come directly within *Daubert*'s purview and give the pharmaceutical industry a substantial interest in the proper application of *Daubert* and Rule 702. To put the Court's decision in this case in context, we provide here a brief discussion of the significance of *Daubert* in pharmaceutical product liability cases. The importance of properly applying *Daubert* in these cases is heightened because the potential for unreliable theories to create meritless liabilities is particularly acute in the pharmaceutical field. As Marcia Angell, M.D., the Executive Editor of the New England Journal of Medicine, explains, "[t]o evaluate whether a product has caused a disease is difficult for nearly anyone. For a jury it is especially difficult, because its members usually have no competence in the area. They are often left to make judgments largely on the basis of the emotional appeals of the lawyers and their expert witnesses."[1/]

[1/] Marcia Angell, *Science on Trial* 204 (1996). Angell further explains that the tort system encourages lawyers under contingency fee arrangements to bring meritless suits, impose burdensome defense costs on defendants, and collect quick settlements. *Id.* at 203. As a result:

> scientific testimony in the courtroom is often at most only marginally related to scientific evidence. To be sure, there are
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> (continued...)

The imposition of unfounded liabilities on pharmaceutical researchers and manufacturers creates serious social costs by adding to the substantial liabilities that pharmaceutical firms already face,[3/] deterring research and innovation, and forcing companies to take safe and effective products off the market.[2/] As one commentator has explained, while "[t]he

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[1/](...continued)

> superficial matters of form that may suggest a resemblance between science in and out of the courtroom. Expert witnesses may wear white coats, be called 'doctor,' purport to do research, and talk scientific jargon. But too often they are merely adding a veneer to a foregone, self-interested conclusion. Sometimes they spin theories that they say are supported by their expertise or experience. Or they may refer vaguely to research. Very often, however, the 'research' is their own and it is unpublished and unavailable. The point is that they are not required to produce their evidence, and they usually do not. The result is a growing gap between scientific reality and what passes for it in the courtroom.

Id. at 132. According to Angell, "[t]he *Daubert* decision was a brave step toward remedying the situation." *Id.*

[3/] *See* W. Kip Viscusi, Michael J. Moore, & James Albright, *The Effect of Products Liability Litigation on Innovation: A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most innovative industries in the economy, has been particularly hard hit by the surge in liability costs.").

[2/] *See* Steven Garber, The Institute for Civil Justice, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 142 (1993) ("Effects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."); Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (Dec. 15, 1989) ("The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially in those having to do with health care.").

economics of the industry impel companies to innovate, . . . liability concerns may steer them away from some types of innovation that appear to pose relatively large liability threats."[10/] Unfortunately, the product areas with the largest potential liability are often those with the greatest potential public health benefits. For example, as early as 1988, the American Medical Association noted that rising liability insurance costs were hindering the testing of new drugs and devices related to pregnancy and contraception.[11/] An FDA expert advisory panel,[12/] the American Academy of

[10/] Garber, *supra* note 9, at 144. The American Medical Association has similarly found that:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.

American Medical Association, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988) [hereinafter *AMA Report*].

[11/] *AMA Report*, *supra* note 10, at 9; *see also* Peter W. Huber, *Liability: The Legal Revolution and Its Consequences* 155 (1988).

[12/] FDA Advisory Panel on Review of Bacterial Vaccines and Toxoids, *Biological Products: Bacterial Vaccines and Toxoids; Implementation of Efficacy Review*, *reprinted in* 50 Fed. Reg. 51002, 51006 (Dec. 13, 1985) ("attempts to improve vaccines further will be hampered" by tort liability).

Pediatrics,[13/] the Institute of Medicine,[14/] and commentators[15/] all agree that liability concerns have impeded pharmaceutical research and development.

Even when drug companies successfully defend against a suit, they (and society) can face substantial costs.[16/] The case of Bendectin, which was at issue in *Daubert* itself, provides a cautionary example.[17/] Bendectin was the only prescription drug ever approved in the United States to treat nausea and vomiting in pregnancy. Introduced in 1956, the drug was used by more than 30 million pregnant women. Beginning in 1969, assertions that Bendectin could produce congenital birth defects began to appear in the scientific literature. Although no scientific study ever proved a causal relationship between Bendectin and birth defects, and the Food and Drug Administration repeatedly affirmed the drug's

[13/] *Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong. 115 (1986) (statement of Dr. Martin H. Smith, President, American Academy of Pediatrics) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

[14/] Institute of Medicine, *Vaccine Supply and Innovation* 11 (1985) ("apprehensions [concerning liability] are a disincentive to investment in the development of new (or improved) immunizing agents"); *id.* at 2 (resolution of liability issues necessary so that "the potential of new technologies [may] be fully realized").

[15/] *E.g.*, Huber, *supra* note 11, at ch. 10.

[16/] Marvin E. Jaffe, *Regulation, Litigation, and Innovation in the Pharmaceutical Industry: An Equation for Safety*, *in* National Academy of Engineering, *Product Liability and Innovation: Managing Risk in an Uncertain Environment* 120, 126 (Janet R. Hunziker & Trevor O. Jones eds.) (1994).

[17/] *See id.*

safety, nearly 1,700 suits were brought against the manufacturer. The manufacturer won nearly every case. Yet despite the overwhelming absence of scientific evidence that its product caused birth defects, the manufacturer had to withdraw Bendectin from the marketplace in 1983, because its annual legal costs were almost as great as its annual sales revenue. Given the fate of Bendectin, "it is unlikely that any new drug will be developed to close the therapeutic gap,"[18] to the detriment of millions of women.

Thus, it is especially important that courts vigilantly exclude testimony that does not meet *Daubert*'s standards. In so doing, courts can minimize the costs of baseless litigation by granting summary judgment where litigants lack valid expert opinions to support their allegations. *See Lust v. Merrell Dow Pharmaceuticals*, 89 F.3d 594, 598 (9th Cir. 1996); *Claar*, 29 F.3d at 500; *O'Conner*, 13 F.3d at 1107; *Porter*, 9 F.3d at 612, 616-17. Even if courts admit scientific evidence, they can apply the factors that *Daubert* outlines to determine whether such evidence, even if admissible, is sufficient to withstand a summary judgment or directed verdict motion. *See Conde*, 24 F.3d at 813-14; *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1073 (6th Cir. 1993), *cert. denied*, 510 U.S. 1193 (1994). As *Daubert* explained, these "safeguards" provide further protections against "a 'free-for-all' in which befuddled juries are confounded by absurd and irrational pseudoscientific assertions." 509 U.S. at 595; *see also Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.) (pre-*Daubert* case cited with approval by *Daubert* holding that plaintiff's scientific evidence was admissible but insufficient to withstand defendant's motion for summary judgment), *cert. denied*, 506 U.S. 826 (1992); *Wade-Greaux*, 874 F. Supp. at 1485 (same).

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[18] *Id.*

III. TO ENSURE THE PROPER APPLICATION OF *DAUBERT*, TRIAL COURT RULINGS ON THE ADMISSIBILITY OF EXPERT SCIENTIFIC OPINIONS SHOULD ONLY BE REVIEWABLE ON APPEAL FOR AN ABUSE OF DISCRETION.

In light of the complex inquiry that district courts must conduct under Rule 702, their decisions on the admissibility of expert testimony should receive considerable deference and be reviewed on appeal only for an abuse of discretion. Indeed, ten courts of appeals have adopted either an abuse of discretion or manifestly erroneous standard of appellate review and accorded district courts wide discretion in applying *Daubert*. *See* cases cited at Pet. App. 6-10.

Applying a de novo standard of appellate review would encourage appellate courts to secondguess district courts and would discourage district courts from excluding improper expert testimony. Whatever consistency de novo review might produce would come at the expense of the meaningful application of *Daubert* and Rule 702 and the expeditious dismissal of baseless liability suits. At the very least, the Court should reject the heightened scrutiny employed by the court of appeals here only for the exclusion of expert testimony, *see* Pet. App. 4a; *see also In re Paoli*, 35 F.3d at 750. Adopting such a one-way ratchet would create a dangerous incentive for district courts to allow unsupported and scientifically flawed testimony to go to the jury.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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